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December 29, 1999 2056 '00 JAN -5 P2:15

Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket No. 97N-484S

Dear Sirs:

*A regulation that would regulate an allograft as a medical device is patently absurd. The device is a mechanical contrivance or appliance. I can't see that animal tissue falls under this aspect of regulation.*

*If you insist on controlling us at least do it rationally.*

Respectfully submitted,

  
William O. Smith, M.D.

WOS:ejd

97N 484S

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**WILLIAM O. SMITH, M.D.**

NEUROSURGERY

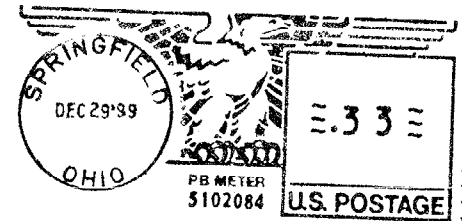
MERCYCREST

MEDICAL ARTS BUILDING

30 W. MCCREIGHT AVE.

SPRINGFIELD, OHIO 45504

ADDRESS CORRECTION REQUESTED



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